Remarks

Status of Claims

Applicants respectfully point out to the Examiner that the listing of claims as stated in the Office Action (2/4/04), on page 1, item 4a is incorrect. More particularly, Applicants note that the Office Action (2/4/04), on page 1, item 4a mistakenly shows claims 95-96, and 126-127 as withdrawn from consideration. Furthermore, Applicants note that claims 95-96, and 126-127 were erroneously listed as withdrawn on the Office Action Summary of the previous Office Action (8/27/03). In response to the Restriction Requirement mailed on November 18, 2002, Applicants elected the claims of Group I (*i.e.*, claims 1-20, 29-52, 61-83, 92-115, and 124-127). Applicants also requested the rejoinder of Group II (*i.e.*, claims 21-28, 53-60, 84-91, and 116-123) and Group III (*i.e.*, claims 128-132), should the claims of Group I be found allowable. Subsequently, Applicants canceled claims 128-132 (Group III) in a Supplemental Response to Office Action mailed June 13, 2003.

Therefore, claims 1-20, 29-52, 61-83, 92-115, and 124-127 are under consideration and claims 21-28, 53-60, 84-91, and 116-123 are withdrawn.

Claim rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 1-2, 4, 8-10, 12, 16, 17, 29-31, 34, 36, 40-42, 44, 48, 49, 61, 62, 65, 66, 68, 72-74, 79, 80, 92-97, 99, 103-105, 107, 111, 112, and 124-127 under 35 U.S.C. 102(b) as allegedly being anticipated by Shau *et al.* (U.S. Patent No. 5,250,295, later referred to as the "'295 Patent"), in light of Shau *et al.* (U.S. Patent No. 5,610,286, later referred to as the "'286 Patent"). More specifically, the Examiner states:

> [s]ince the reference anticipates the claims because more than half of the amino acids between the reference and instant protein are identical, it would be difficult to make an antibody to the polypeptide of the reference that would not bind to the instant polypeptide as set forth in SEQ ID NO:2. Therefore, it would be difficult for one of ordinary skill in the art to make an antibody to the protein of the prior art reference, which did not infringe on the antibody limitations of the instant claims.

See Office Action (2/4/04), page 3, lines 13-18.

Applicants respectfully disagree and traverse.

The Federal Circuit has held that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreover, section 2131 of the Revised 8th edition of the M.P.E.P.

reiterates this standard at page 2100-70. Therefore, for a rejection under 35 U.S.C. § 102 to be valid, every element of the present invention must have been disclosed prior to the filing of the present application. Applicants assert that every element of the present invention was not disclosed prior to the filing of the present application and that the antibodies of the prior art do not fall within the scope of what is claimed as the present invention.

The M.P.E.P. § 2111 explains that during examination "claims must be given their broadest reasonable interpretation." Importantly, § 2111 of the M.P.E.P., citing *In re Cortright,* further explains that "[t]he broadest interpretation of the claims must also be consistent with the interpretation those skilled in the art would reach." *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). We submit herewith a Declaration under 37 C.F.R. § 1.132 by Dr. Viktor Roschke (hereinafter, the "Roschke Declaration") that clearly indicates that, on the basis of the meaning of the term "specifically binds" to one skilled in the art, the prior art antibody disclosed in the Shau *et al* '286 Patent does not fall within the scope of what is claimed. In other words, the prior art antibody does not anticipate the claimed invention.

In his declaration, Dr. Roschke defines how the phrase "specifically binds" is understood by those of skill in the antibody arts. He states "scientists who routinely work with antibodies consider an antibody that is 'specific' for one member of a protein family as one that does not appreciably bind, i.e. cross-react, with other members of that family (i.e. paralogues) irrespective of the level of sequence identity among family members." He illustrates this fact by giving examples from the *Santa Cruz Biotechnology, Inc. 1997/98 Research Antibodies Catalog* (Exhibit F of Roschke Declaration) that describe antibodies that are specific for particular proteins. These antibodies are described as being specific for a particular protein and being non cross-reacting with other members of the protein family. *See* Roschke Declaration, paragraphs 8-9.

Upon consideration of the information detailed above and in light of the art understood meaning of the phrase "specifically binds," one of skill in the art would conclude that the antibodies described in the Shau *et al.* '286 Patent are not an antibodies that specifically bind to a protein whose sequence consists of amino acid residues 1 to 271 of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit No. 97157 (or a fragment thereof). This conclusion would be based on the fact that the antibodies described in the Shau *et al.*'286 Patent bind NKEF A and B proteins, paralogues of NKEF C/the protein of the present invention. Moreover,

the antibodies in the Shau *et al.* '286 Patent may or may not bind NKEF C and such a determination could not be predicted and would have to be determined experimentally. However, irrespective of the outcome of such an experiment, based on the Roschke Declaration, the mere fact that said antibodies bind NKEF A or B means they cannot be antibodies that specifically bind NKEF C.

The Roschke Declaration demonstrates that one of skill would not interpret an antibody that binds a paralogue of a protein as an antibody that specifically binds said protein. The prior art in this case teaches antibodies that bind to paralogues (NKEF A and B) of the polypeptide of the present invention. Therefore, the prior art does not satisfy the element of "specifically" binding the polypeptide of the present invention as it would be interpreted by one of skill in the art. Thus, the claimed antibodies cannot be anticipated by the antibodies directed against NKEF A and B described in the '286 Patent because only antibodies specifically recognizing NKEF C are claimed.

In view of the remarks submitted herewith, Applicants believe that the rejections of the Examiner have been overcome. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim rejections under 35 U.S.C. § 103(a)

A. Claims 3, 11, 35, 43, 67, 75, 85, 98, 106, and 117 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shau *et al* (See, above, later referred to as "Shau"), in view of Lerner (1982, later referred to as "Lerner"), and Harlow et al. (1988, later referred to as "Harlow"). *See*, Office action (2/4/04), page 3, item 7a.

Applicants respectfully disagree and traverse.

In order for a rejection under 35 U.S.C. § 103(a) to be valid, three criteria must be met:

a) there must be some suggestions or motivation to modify or to combine reference teachings;

b) there must be a reasonable expectation of success; and

c) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

((*See,* M.P.E.P. 706.02(j)) (emphasis added).

As discussed above, Shau does not disclose an antibody that specifically binds a protein whose sequence consists of residues 1 to 271 of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157, or a fragment thereof. In the absence of knowledge of the polypeptide of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157, it would have been impossible to make an antibody that specifically binds the polypeptide of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157. Furthermore, none of the supplemental references, Lerner and Harlow, provide the missing information (namely the sequence of SEQ ID NO:2 or the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157). Therefore, there would be no motivation or suggestion to use the teachings of Shau, alone or in combination with any other reference, to obtain monoclonal antibodies that specifically bind to the NKEF C polypeptide of the present invention.

Accordingly, Applicants respectfully request that the rejection of claims 3, 11, 35, 43, 67, 75, 85, 98, 106, and 117 under 35 U.S.C. § 103 be reconsidered and withdrawn.

B. Claims 5-7, 13-15, 37-39, 45-47, 69-71, 76-78, 87-89, 100-102, 108-110, and 119-125 were rejected under 35 U.S.C. § 103 as being unpatentable over Shau *et al* (*See*, above, later referred to as "Shau") in view of Queen (U.S. Patent No. 5,530,101, later referred to as "Queen"). *See*, Office action (2/4/04), page 4, item 7b.

As discussed above, Shau does not disclose an antibody that specifically binds a protein whose sequence consists of residues 1 to 271 of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157, or a fragment thereof. In the absence of knowledge of the polypeptide of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157, it would have been impossible to make an antibody that specifically binds the polypeptide of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157. Furthermore, the Queen reference does not provide the missing information (namely the sequence of SEQ ID NO:2 or

the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157). Therefore, there would be no motivation or suggestion to use the teachings of Shau, alone or in combination with Queen, to obtain the antibodies that specifically bind to the NKEF C polypeptide of the present invention. Accordingly, Applicants respectfully request that the rejection of claims 5-7, 13-15, 37-39, 45-47, 69-71, 76-78, 87-89, 100-102, 108-110, and 119-125 under 35 U.S.C. § 103 be reconsidered and withdrawn.

C. Claims 18-20, 50-52, 81-83, 100-102, and 113-115 were rejected under 35 U.S.C. § 103 as being unpatentable over Shau et al (*See*, above), in view of Lerner (1982, later referred to as "Lerner"), and Harlow et al. (1982, later referred to as "Harlow") as applied to claims 3, 11, 35, 43, 67, 75, 85, 98, 106, and 117 above, further in view of Servier et al. (1981, later referred to as "Servier"). *See*, Office action (2/4/04), page 5, item 7c.

As discussed above, '295 and '286 Patents do not disclose an antibody that specifically binds a protein whose sequence consists of residues 1 to 271 of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157, or a fragment thereof. In the absence of knowledge of the polypeptide of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157, it would have been impossible to make an antibody that specifically binds the polypeptide of SEQ ID NO:2 or a protein whose sequence consists of the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157. Furthermore, none of the supplemental references, Lerner, Harlow, and Servier, provide the missing information (namely the sequence of SEQ ID NO:2 or the amino acid sequence of the full length polypeptide encoded by the cDNA contained in ATCC Deposit 97157). Therefore, there would be no motivation or suggestion to use the teachings of Shau, alone or in combination with any other reference, to obtain the antibodies that specifically bind to the NKEF C polypeptide of the present invention. Accordingly, Applicants respectfully request that the rejection of claims 18-20, 50-52, 81-83, 100-102, and 113-115 under 35 U.S.C. § 103 be reconsidered and withdrawn.

Conclusion

Applicants believe that this application is in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the issuance of this application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425.

Dated: 31 March 2004

Respectfully submitted,

By _____

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